



Safety Pharmacology Society  
8<sup>th</sup> Annual Meeting Program  
Madison, Wisconsin U.S.A.

**Monday, September 22, 2008—Continuing Education Day**

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Please note that participation in the Continuing Education course requires attendees to register for the courses. See Continuing Education site for course descriptions.

<http://www.safetypharmacology.org/am2008/ce.asp>

**Morning Courses:** [CE \(1\)](#), [CE \(2\)](#), [CE \(3\)](#), [CE \(4\)](#)

Morning Courses include a continental breakfast and refreshments during the break.

Morning Course Schedule (may vary depending on course).

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7:30 AM

**Continental Breakfast**

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8:00 AM

**Course in Session**

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10:00 AM

**Break**

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10:15 AM

**Course in Session**

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12:00 Noon

**Course Concludes** – Lunch on own for Morning CE Course participants.

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**Afternoon Courses:** [CE\(5\)](#), [CE\(6\)](#), [CE\(7\)](#), [CE\(8\)](#)

Afternoon Courses include a box lunch that can be picked up in the respective meeting room at 12:30 PM and refreshments during the break. Afternoon Course Schedule (may vary depending on course).

1:00 PM

**Course in Session**

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3:00 PM

**Break**

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3:15 PM

**Course in Session**

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5:00 PM

**Course Concludes**

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5:00 PM

**Welcoming Reception**

Rooftop Terrace



This hour and half reception will be an opportunity to see old friends and make new acquaintances.

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6:30 PM

**All SPS Hosted Functions Adjourn**

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**Tuesday, September 23, 2008**

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7:30 AM

**Continental Breakfast**  
Exhibit Hall

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8:15 AM

**Welcome and Announcements**  
Ian MacKenzie, PhD, President of the Safety Pharmacology Society  
Ballroom AB

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8:30 AM

**President's Keynote Address**  
Craig T. January, MD, PhD, FACC University of Wisconsin-Madison, Madison, WI,  
USA  
**Discovery of hERG: Historical Perspectives and Contemporary Concerns**  
Ballroom AB

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9:30 AM

**Break**

Exhibit Hall

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10:00 AM

**A. Translational: Biomarkers** (Session Chair Mike Engwall)

Ballroom D

**ECG and Blood Pressure as Biomarkers—Orthostatic Hypotension**

Speaker: Nancy Poy, DVM, Pfizer, Groton, CT, USA

**Ultrasound as a Biomarker of Cardiovascular Function: Valves, Hypertrophy, and Vascular**

Speaker: Brian Hoit, MD, Professor of Medicine, Case Western Reserve and Department of Cardiology and Internal Medicine, Case Western Reserve University and University Hospitals of Cleveland, Cleveland, OH, USA

**Serum Chemistry Parameters as Cardiovascular Biomarkers**

Speaker: David Watson, PhD, Research Advisor Investigative Toxicology, Eli Lilly & Co., Indianapolis, IN, USA

**B. Emerging Technologies** (Session Co-Chairs, Anthony Bahinski and Craig January)

Ballroom AB

**Stem Cells Session Overview:**

The field of stem cell research has been rapidly accelerating in the last several years. The development of validated human cell-based *in vitro* safety screens has the potential to facilitate earlier attrition of compounds with unacceptable safety profiles. This session will focus on recent efforts to develop a new source of pluripotent stem cells from somatic tissue and on the development of *in vitro* models using stem cell derived human tissue for drug safety evaluation.



**Human induced Pluripotent Stem (iPS) Cells: Implications for Drug Screening**

Speaker: James S. Thomson, VMD., PhD, University of Wisconsin-Madison, Madison, WI, USA

**Human Pluripotent Stem Cell-Derived Cardiomyocytes for Safety Pharmacology Applications**

Speaker: Timothy J. Kamp, MD, PhD, University of Wisconsin-Madison, Madison, WI, USA

**Human Embryonic Stem Cells Provide a Robust Source of Neural Cells for Drug Discovery and Toxicity**

Speaker: Steven L. Stice, PhD, The University of Georgia and Aruna Biomedical Inc., Athens, GA, USA

**C. Integrated Systems Physiology** (Session Co-Chairs: Maxim Soloviev and Franz Hock)  
Ballroom C

**Introduction to Chronobiology**

Speaker: Prof. Dr. med. Dr. h.c. Björn Lemmer Institut für Experimentelle & Klinische Pharmakologie & Toxikologie

**Chronopharmacokinetics**

Speaker: Prof. Dr. med. Dr. h.c. Björn Lemmer Institut für Experimentelle & Klinische Pharmakologie & Toxikologie

**Vascular Consequences of Sleep Disordered Breathing**

Speaker: Barbara Morgan, PhD, PT, University of Wisconsin-Madison, Madison, WI, USA

**Mechanisms of Intermittent Hypoxia Induced Respiratory Plasticity: A Guide for Novel Therapeutic Approaches to Sleep Apnea?**

Speaker: Gordon Mitchell, PhD, University of Wisconsin-Madison, Madison, WI, USA



12:00 Noon

**LUNCH Break:** The buffet lunch will be serviced in the Exhibit Hall.

**Poster Viewing:** All Attendees are encouraged to visit the exhibit hall to view the posters and to learn about the latest technology and services available to the field of safety pharmacology.

**Poster Presentation Judging.**

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2:00 PM

**A. Invited Oral Communications 1**

Ballroom AB

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|---------|---|
| 2:00 PM | 1. Presentation selected from submitted abstracts |
| 2:15 PM | 2. Presentation selected from submitted abstracts |
| 2:30 PM | 3. Presentation selected from submitted abstracts |
| 2:45 PM | 4. Presentation selected from submitted abstracts |

**B. Invited Oral Communications 2**

Ballroom C

- |         |   |
|---------|---|
| 2:00 PM | 1. Presentation selected from submitted abstracts |
| 2:15 PM | 2. Presentation selected from submitted abstracts |
| 2:30 PM | 3. Presentation selected from submitted abstracts |
| 2:45 PM | 4. Presentation selected from submitted abstracts |
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3:00 PM

**Break**

Exhibit Hall

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3:30 PM

**A. Translational** (Session Chair, Ian MacKenzie)  
Ballroom D

**EEG: Relevance in the Evaluation of Sedation and Seizure Risk**

Speaker: Joseph Arezzo, PhD, Albert Einstein College of Medicine, Bronx, NY, USA

**Using Preclinical Electrophysiologic Data to Impact the Early Clinical Drug-Development Program and Validation of Preclinical Tests to Impact Regulatory Decision Making**

Speaker: Phillip Sager, MD, CardioDX, Wilmington, DE, USA

**B. Emerging Technologies** (Session Chair, Anthony Bahinski)  
Ballroom AB

**Session Overview:**

With increasing emphasis on mechanistic studies, the emergence of biotherapeutics and earlier involvement in the drug discovery process, there is an increasing need for novel *in vivo* models beyond the core battery of safety pharmacology assays. This session will focus on recent efforts to use RNAi and transgenic animals to provide early insights into target safety.

**Novel *In-vivo* models—Transgenic Models**

Speaker: Sandra J. Engle, PhD, Pfizer, Inc., Groton CT, USA

**Novel *In-vivo* models—Non Viral Delivery of RNAi**

David L. Lewis, PhD, Mirus Bio Corporation, Madison WI, USA

**Novel *In-vivo* models—KO Rat Models**

Speaker: Alexandre Fraichard, PhD, MBA, genOway, Lyon, France

**C. Integrated Systems Physiology** (Session Chair, Ted Baird)  
Ballroom C

**Neural Regulation of the Gastrointestinal Tract**

Speaker: Gary M. Mawe, PhD, University of Vermont, Burlington, VT, USA



**Mechanisms of Visceral/Cardiac Pain Perception**

Speaker: Robert D. Foreman, PhD, Department of Physiology, University of Oklahoma Health Sciences Center, Oklahoma City, OK, USA

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4:00 PM

**Exhibit Hall Closed**

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5:00 PM

**All SPS Functions Adjourn**

**Wednesday, September 24, 2008**

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7:30 AM

**Continental Breakfast**  
Exhibit Hall

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8:00 AM

**A. Translation: Issues in Personalized Medicine** (Session Chair, Dusty Sarazan)  
Ballroom D



**Mommies Cry Too: A Personal Story of Surviving Post Partum Depression Medication and an Unknown Cytochrome P450 Deficiency**

Speaker: Carolyn Brink (<http://www.mommiescrytoo.com>)

**The Science Behind the Story: CYP450 Polymorphisms in Patients**

Speaker: Steven Wrighton, PhD, Eli Lilly & Co., Indianapolis, IN, USA

**B. Emerging Strategies—Advancement in Modeling of Drug-Induced Torsades des Pointes** (Session Co-Chairs, Alan Bass, Neils-Christian Ganderup and Josh Burton)  
Ballroom AB

**Progress Towards Advancement of Preclinical Modeling for Drug-Induced Torsades des Pointes**

Speaker: Alan Bass, PhD, Schering-Plough, Kenilworth, NJ, USA

**Ca<sup>2+</sup> Handling by Ventricular Myocytes is a predictor of Vulnerability to Torsade de Pointes in Drug-Induced Long QT Type 2**

Speaker: Guy Salama, PhD, University of Pittsburg, Pittsburg, PA, USA

**Alternative Mechanisms of Drug-Induced QT Prolongation—Beyond hERG**

Speaker: Jean-Pierre Valentin, AstraZeneca, Macclesfield, UK

**Emerging Issues in Safety Pharmacology—Survey of Industry Identifying Consortia Projects**

Speaker: Neils-Christian Ganderup, M.Sc, Ellegaard Göttingen Minipigs, Dalmose, Denmark

**C. Integrated Systems Physiology** (Session Chair, Scott Mittelstadt)  
Ballroom C

**Mechanisms of Platelet-Mediated Thrombosis**

Speaker: John Folts, Professor of Medicine, Director, Coronary Thrombosis Research and Prevention Laboratory, University of Wisconsin-Madison, Madison, WI, USA

**Central Mechanisms of Baroreflex Control of Blood Pressure**

Speaker: Jeanne Seagard, PhD, Department of Anesthesiology, Zablocki Department of Veterans Affairs Medical Center, Medical College of Wisconsin, Madison, WI, USA



This presentation will examine central components of baroreflex control of blood pressure, focusing on the integration of baroreceptor afferent input by neurons in the brainstem. This is a pivotal regulatory moment, because the signal conditioning at these gateway synapses determine the magnitude, pattern and duration of the baroreceptor signals transmitted to distal synapses in the central network to coordinate baroreflex output and ensuing control of blood pressure. Mechanisms involved in the integration and transmission of baroreceptor input, including neurotransmitters and modulators of baroreceptor input, will be discussed.

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9:30 AM

**Break**

Exhibit Hall

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10:00 AM

**A. Translational** (Session Chair, Dusty Sarazan)

Ballroom Room AB

**Clinical Bridging Studies: How Does Gender and Race Influence Personalized Medicine?**

Speaker: Jon Ruckle, PhD, Covance, Honolulu, HI, USA

**B. Emerging Strategies** (Session Chair, Alan Bass)

Ballroom D

**Emerging Drug Safety: Combating Attrition in Discovery as a Way of Mitigating Failure in Development**

Speaker: Alan S. Bass, PhD, Drug Safety, Schering-Plough, Kenilworth, NJ, USA

**Frontloading Safety Pharmacology in Support of Selecting the Best Compounds for Development**

Speaker: Silvana Lindgren, PhD, Safety Assessment, AstraZeneca R&D, Sodertalje, Sweden



**C. Integrated Systems Physiology** (Session Chair, Dennis Murphy)  
Ballroom C

**Ventilatory Control: Carotid Body Plasticity and Pharmacology**

Speaker: Gerald Bisgard, DVM, PhD, Professor Emeritus Comparative Biosciences, University of Wisconsin-Madison, Madison, WI, USA

**Effects of Gender and Age on Ventilatory Control**

Speaker: Mary Behan, PhD, Veterinary Medical School, University of Wisconsin-Madison, Madison, WI, USA

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11:00 AM

**Safety Pharmacology Society Annual Meeting & Awards**  
Ballroom AB

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12:30 PM

**Lunch Break:** The buffet lunch will be serviced in the Exhibits Hall.

**Poster Viewing:** All Attendees are encouraged to visit the Exhibit Hall to view the posters and to learn about the latest technology and services available to the field of safety pharmacology.

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2:00 PM

**A. Invited Oral Communications 3**  
Ballroom AB



- 2:00 PM 1. Presentation selected from submitted abstracts
- 2:15 PM 2. Presentation selected from submitted abstracts
- 2:30 PM 3. Presentation selected from submitted abstracts
- 2:45 PM 4. Presentation selected from submitted abstracts

**B. Invited Oral Communications 4**

Ballroom C

- 2:00 PM 1. Presentation selected from submitted abstracts
- 2:15 PM 2. Presentation selected from submitted abstracts
- 2:30 PM 3. Presentation selected from submitted abstracts
- 2:45 PM 4. Presentation selected from submitted abstracts

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3:00 PM

**Break**

Exhibit Hall

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3:30 PM

**A. Translation Track** (Session Chair, Kristy Bruse)

Ballroom AB

**Predictivity Model/Frame—What Are the Tools and How Are They Used for Predicting Liability?**

Speaker: Rob Wallis, PhD, Pfizer, Sandwich, UK

**Panel Discussion—Predictivity and Personalized Medicine**

Speakers: Rob Wallis, PhD, Pfizer, Sandwich, UK, Steven Wrighton, Indianapolis, IN, USA,

Peter K.S. Siegl, PhD, Blue Bell, PA, USA, and John E. Koerner, Silver Spring, MD, USA



**B. Emerging Strategies—Integration of Toxicity and Safety Pharmacology Studies in Risk Assessment** (Session Chair, Sharon Rowton and Alfred Botchway)

Ballroom D

**Single vs. Multi Dose Studies**

Speaker: Will Redfern, PhD, Associate Principal Scientist, Safety Pharmacology UK, Global Safety Assessment, AstraZeneca R&D, Alderley Park, Cheshire, UK

**Case Studies to Answer Why You Would/Would Not Consider Cross Discipline Assessment**

Speaker: TBD

**CV, CNS, Respiratory: How to Use Established Models for Combined Risk Assessment**

Speaker: Mary-Jeanne Kallman, PhD, Eli Lilly, Greenfield, IN, USA

**C. Integrated Systems Physiology** (Session Chair, Ted Baird)

Ballroom C

**Role of Visual Electrophysiology in Preclinical Testing**

Speaker: James Ver Hoeve, PhD, University of Wisconsin-Madison, Madison, WI, USA

**Long-Term Regulation of Blood Pressure: Endocrine and Renal**

Speaker: Kim Hoagland, PhD, Merck & Co., Inc., West Point, PA, USA

**Drug-Induced Activation of Immune Function: Mechanisms and Potential Adverse Effects**

Speaker: Curtis Maier, PhD, GlaxoSmithKline Pharmaceuticals, King of Prussia, PA, USA

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4:00 PM

**Exhibit Hall Closed**

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5:00 PM

**All SPS Hosted Functions Adjourn**

## **Thursday, September 25, 2008**

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8:15 AM

**Introduction to Biologics** (Session Chair, Tom Beck)

Ballroom AB

**Introduction to Biologics**

Speaker: Hugo Vargas, PhD, Amgen, Thousand Oaks, CA, USA

This presentation will give an overview of the commonly encountered biologic molecules and touch on potential complexities these types of molecules present for safety pharmacology.

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8:45 AM

**Point-Counter Point: Integration of Safety Pharmacology Endpoints in Toxicology Studies for Biologics Testing** (Session Chair, Tom Beck)

Ballroom AB

Speakers: Derek Leishman, PhD, Lilly Research Laboratories, Greenfield, IN, USA and Noel Dybdal, PhD, Genentech, Southern San Francisco, CA, USA

This discussion will present the advantages and disadvantages of incorporation of Safety Pharmacology endpoints into toxicology studies conducted with large molecules. Each speaker will present his or her view and critically evaluate the others views.

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9:30 AM

**Break**

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10:00 AM

**Biologics and Safety Pharmacology: A regulatory perspective**  
(Session Chair, Gregory Friedrichs)

Speaker: Michael S. Orr, PhD, DABT, Pharmacology Reviewer, U.S. Food and Drug Administration, Silver Spring, MD, USA

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11:00 AM

**Biologics and Safety Pharmacology: A clinical perspective**  
(Session Chair, Carrie Markgraf)  
Ballroom AB

Speaker: Stephen Flach, PhD, Covance Madison, Madison, WI, USA

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11:45 AM

**Closing Remarks**  
Ballroom AB

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12:00 Noon

**Annual Meeting Adjourns**